

MAY 19 2005



10111 WEST JEFFERSON BOULEVARD, CULVER CITY, CALIFORNIA 90232
TELEPHONE 888-648-8835 FAX 310-837-0468 www.inovelmedical.com

April 29, 2005

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510(k) Summary**Submitter:**

Inovel LLC
10111 W. Jefferson Blvd.
Culver City, CA 90232-3509

Contact:

William Wawrzyniak
Director Quality Assurance
Telephone: 866-546-6835 Ext. 705
Fax: 310-837-0468
E-mail: billw@inovelmedical.com

Trade Name:

Inovel Health Care N95 Particulate Respirators and Surgical Masks, various models.

Model Numbers:

3000N95-XS, 3001N95-S, 3002N95-M, 3003N95-L, 3004N95-LP, 3101N95-S, 3102N95-M/L, 3104N95-LP, FRN95-SEZ, FRN95-MLEZ, FRN95-AEZ, FRN95-XS, FRN95-S, FRN95-ML and FRN95-A

Common Name:

Health Care N95 Particulate Respirator and Surgical Mask.

Classification:

Name – Surgical Apparel, as described in 21 CFR 878.4040.
Device Class – Class II
Product Code – MSH
CFR Section – 21 CFR 878.4040

Substantial Equivalency:

Inovel Health Care N95 Particulate Respirators and Surgical Masks are found to be substantially equivalent to the Aearo Co. Pleats Plus mask model 1050 and 1050S [(510(k)K041855] and Gerson Isolair APR type N95 mask model 2735 [(510(k)K960778)]. These two products have also been tested and approved by NIOSH as N95 Respirators.



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510(k) Summary (Continued)

Description:

The Inovel type N95 Healthcare Particulate Respirators and Surgical Masks are constructed from a nonwoven spunbond used in the inner and outer cover. The polypropylene melt blown filter media is layered between the inner and outer cover. The head strap is made of a non-latex rubber stapled to the mask (for double headband) and polyester elastic (for single head strap) which is sewn to the mask. The inside nosepiece is a closed cell foam.

The Inovel type N95 Healthcare Particulate Respirators and Surgical Masks are approved by NIOSH in accordance with 42 CFR 84. The certification numbers are TC-84A-4101 and TC-84A-4103 (for single head strap) and TC-84A-4100 and TC-84A-4102 (for double head straps) for a type N95 Particulate Respirator.

The type N95 must meet the prescribed test criteria which specifies the use of 0.055 to 0.095 micron diameter challenge and requiring a 95% efficiency or better. The masks are resistant to synthetic blood as per ASTM F 1863 Standard Test method for Resistance of Medical Face Mask to Penetration by Synthetic Blood, conducted by Nelson Laboratories. Breathing resistance was tested by NIOSH in accordance to 42 CFR 84.

Intended Use:

The various models of Inovel/Cardinal Type N95 Healthcare Particulate Respirators and Surgical Masks meet CDC Guidelines for TB Exposure Control within healthcare facilities. These devices are also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.

Limitations:

These products do not eliminate the wearer from any risk of contracting any type of disease or infection. The mask should be changed immediately if contaminated with blood or body fluids.

Comparison of Predicate Devices:

The outside cover color of the previously cleared devices are white and the Inovel are blue or multi-color. The head strap color of the cleared device is yellow and the Inovel device models are various colors as described in pages 2 - 2 through 2 - 5.

The Inovel type N95 Healthcare Particulate Respirators and Surgical Masks incorporate a highly efficient filter media and is 95% efficiency or better against aerosols that have a count median diameter of 0.055 - 0.095 microns which was scientifically established as the most penetrating particle size. The legally marketed devices previously cleared 510(k) are manufactured from similar materials.



10111 WEST JEFFERSON BOULEVARD, CLEVELAND CITY, CALIFORNIA 90232
 TELEPHONE 888-648-8835 FAX 310-837-0468 www.inovelmedical.com

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510(k) Summary (continued)

Device and Predicate Devices Descriptions/ Comparisons

Description	Inovel Health Care N95 Particulate Respirators and Surgical Masks, various models (15)	Gerson Isolair APR Type N95 model 2735, 510(k) K960778	Aearo Co. Pleats Plus 1050 and 1050S, 510(k) K041855
Materials			
Fabrics	Spunbond polypropylene, Meltblown polypropylene	White nonwoven polyester, Meltblown polypropylene	White spunbond polypropylene, Meltblown polypropylene
Nosepiece	Polyethylene foam	Closed cell foam	Tie wire
Headband	Various colors elastic, latex free	Yellow elastic, latex free	White Elastic, latex free
Specification & Dimensions	Various sizes (14.75" - 15.625" circumference)	Small (13.75" circumference)	Small (13.5" circumference) Large (15.5" circumference)
Mask Style	Molded Cup	Molded Cup	Flat pleated
Design Features	Dual synthetic rubber or single elastic head strap	Dual elastic head strap	Dual elastic head strap
NIOSH Certification#	TC-84A-4100 thru TC-84A-4103	TC-84A-160	TC - 84A - 2630

Risks to Health

Performance Characteristics	Test Method	Acceptance criteria/ Results	Predicate Device Results	Predicate Device Results
		Inovel Health Care N95 Particulate Respirators and Surgical Masks various models (15)	Gerson Isolair APR Type N95 model 2735, 510(k) K960778	Aero Co. Pleats Plus 1050 and 1050S, 510(k) K041855
Fluid Resistance Performance (mmHg)	ASTM 1862 - 00a @ 160 mm Hg	29 of 32 pass/ 32 of 32 pass	32/32 pass	31/32 pass @ 120 mmHg
Flammability Class	16 CFR 1610	Flame spread must be within upper and lower limits/ No flame spread on 10 of 10 samples, meets Class I	Meets Class I	Meets Class I
Filter Efficiency (%)	NIOSH, 42 CFR Part 84	≥ 95% Efficient/ average 99.11% efficient of 20 samples (model 3000N95-XS)	Average 98.86% efficient of 20 samples	Average 99.11% efficient of 20 samples
Breathing Resistance (mm H ₂ O)	NIOSH, 42 CFR Part 84	≤ 35.0 mm H ₂ O @ 85 lpm/ average 3.5 mm H ₂ O @ 85 lpm of 3 samples	Average 15.2 mm H ₂ O on 3 samples	Average 3.5 mm H ₂ O on 3 samples
Biocompatibility	ISO 10993 - 1	Cytotoxicity, score of 2 or less/ Score of 0	N/A	Score of 0
		Sensitization, Grade 1 (no different than control)/ Grade 1	N/A	Score of 0 (closed patch test)
		Primary Skin Irritation, Negligible/Negligible	N/A	Negligible



10111 WEST JEFFERSON BOULEVARD, CULVER CITY, CALIFORNIA 90232
 TELEPHONE 888-546-6835 FAX 310-337-0468 www.inovelmedical.com

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510(k) Summary (Continued)

Performance Tests:

These products were tested and certified by NIOSH as an approved N95 Respirator. It meets all the requirements prescribed in 42 CFR Part 84 and is assigned TC-84A-4100 through TC-84A-4103.

Tests Performed

Laboratory

- | | |
|--------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1. Fluid Resistance - Resistance of Liquid (Synthetic Blood Penetration Resistance) ASTM F 1862. | Nelson Laboratories |
| 2. Filtration Efficiency (Particulate and Bacterial) 42 CFR Part 84 | NIOSH |
| 3. Differential Pressure (Delta P) - Breathing Resistance 42 CFR Part 84 | NIOSH |
| 4. Flammability 16 CFR 1610 (Class 1) | Nelson Laboratories |
| 5. Biocompatibility | |
| • Cytotoxicity ISO 10993 - 5 | Nelson Laboratories |
| • Sensitization ISO 10993 - 10 | Northview Pacific Laboratories, Inc.
(Coordinated by Nelson Laboratories) |
| • Irritation ISO 10993 - 10 | Northview Pacific Laboratories, Inc.
(Coordinated by Nelson Laboratories) |

Safety/ Effectiveness:

The devices have a filtration equivalent to the previously cleared Aeareo Co. Pleats Plus model 1050 and 1050S and Gerson Isolair APR model 2735 Particulate Respirator and Surgical mask. They are NIOSH approved and meet the CDC guidelines for TB.

Conclusion:

The basic construction and material used in the cleared devices is basically the same as in the new devices. The cleared devices and the new devices are also approved by NIOSH, and meets all other required tests. The Inovel type N95 Healthcare Particulate Respirators and Surgical Masks are substantially equivalent to those listed on page 2 - 7.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2005

Inovel, LLC
C/O Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K051182

Trade/Device Name: Inovel Health Care N95 Particulate Respirators and
Surgical Masks, Various Models
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: May 6, 2005
Received: May 9, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051182

Device Name: Inovel Health Care N95 Particulate Respirators and Surgical Masks, various models.

Indications for Use:

The various models of Inovel/Cardinal Type N95 Healthcare Particulate Respirators and Surgical Masks meet CDC Guidelines for TB Exposure Control within healthcare facilities. These devices are also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.


Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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510(k) Number. K051182